the WOOD BURDITT group

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BY COURIER/Monday Delivery

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

Date:	April 28, 2006
Name of Petitioner:	ACH Food Companies, Inc.
Post Office Address	7171 Goodlett Farms Pkwy. Memphis, TN 38016
Subject of the Qualified Health Claim Petition	**REDUCED RISK of HEART DISEASE from CORN OIL and CORN OIL-CONTAINING PRODUCTS**

Dear ONPLDS Representative:

The undersigned, Richard O. Wood, Regulatory Counsel for the Petitioner identified above, submits this Qualified Health Claim Petition pursuant to FDA Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements. The Petition is in two parts and is entitled: REDUCED RISK of HEART DISEASE from CORN OIL and CORN OIL-CONTAINING PRODUCTS

The documents provided, and constituting the entire Health Claim Petition, are:

1. This Letter and Attachment – 4 pages
2. Petition Part I -- The Petition (1 Volume) and Part I Attachments (1 Volume)
3. Part II -- The Petition's Summary of Scientific Data/Evidence Analysis[1] (1 Volume) and Part II Appendices (1 Volume)
4. Evidence Analysis Reference Volumes 9 and 10 (of 10) (the other 8 volumes of references have been provided to ONPLDS previously)
5. CD ROM disks with PDF files of all documents in items above

[1] The Summary of Scientific Data/Evidence Analysis was prepared in accordance with FDA's "Interim Evidence-Based Ranking System for Scientific Data"

In order to assure that the format and sequence of this Petition are consistent with the requirements of 21 C.F.R. §101.70(f) and (g), and to facilitate ONPLDS' review for purposes of sufficiency of the information provided, those sections are quoted in italicized font below. The citation to Part I or Part II of the Petition accompanies each requirement.

	Petition	
21 CFR §101.70(f)	Part I	Part II
A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of § 101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of § 101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS), listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.	Chapter II	
B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.		Part II was prepared pursuant to FDA's Interim Evidence-Based Ranking System for Scientific Data
The summary shall state what public health benefit will derive from use of the claim as proposed.	Chapter I	Entire Document addresses the benefit
If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.	Not Applicable	
The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials.		Chapter 3
Issues addressed in the summary shall include answers to such questions as: *1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?*		Pages 35-36

	Petition	
21 CFR §101.70(f)	Part I	Part II
2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?		Page 37
3. Are there certain populations that must receive special consideration?	Not Applicable	
4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?		Page 37
In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.		Pages 39-40
If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).	Not Applicable	
If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.	Pages 6-7;22	Page 5
Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in § 101.14(a)(2).	Page 6	
C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC), where available. If no AOAC method is available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.	Chapter VII Attachments 6 (USDA Nutrient Database) and 7 (Codex) for corn oil	
D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:	Chapter VIII	
1. A brief capsulized statement of the relevant conclusions of the summary, and		Chapter 1

	Petition	
21 CFR §101.70(f)	Part I	Part II
2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.		Pages 39-40
E. The petition shall include the following attachments: *1. Copies of any computer literature searches done by the petitioner (e.g., Medline).*		Appendix A
2. Copies of articles cited in the literature searches and other information as follows: *a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.*		Reference Volumes
b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).		Page 39
c. All information pertaining to the US population.		Reference Volumes
F. The petitioner is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.	Chapter X	
Yours very truly, *Petitioner _____* *By _____* *(Indicate authority)*	See below	
(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified.	See above	
If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.	8 Reference Volumes have previously been submitted to ONPLDS	

Yours very truly,
Petitioner ACH Food Companies Inc.

By _____
Richard O. Wood
Regulatory Counsel for Petitioner